Simplified One-Handed Preemptive Medical Procedure Site Dressing to Prevent Sharps Injuries and Exposure to Bloodborne Pathogens

by

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CROSS-REFERENCE TO RELATED APPLICATIONS

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BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to dressings for broken skin, such as ulcers, surgical interventions, vaccinations, or needle puncture sites on humans or animals, which permit application of the dressing in compliance with needlestick prevention guidelines and further provides access to the lesion without removal of the dressing. More specifically, this invention relates to the facilitation of one-handed application of such dressings by providing a dressing and method whereby the dressings can be placed on the procedure site prior to the performance of an invasive medical procedure.

2. Description of the Related Art

Healthcare workers are at risk of serious infections if exposed to pathogens which are commonly present on needles and other sharp devices after such devices are used to break, cut, or puncture the skin of a patient. It is widely recognized that body fluids containing bloodborne pathogens are a serious vector of transmission of infectious diseases. The spread

of bloodborne pathogens to clinical practitioners and others by contact with the body fluids of an infected patient is an inherent risk that is routinely taken when conducting procedures involving skin punctures and releasing blood and other body fluids. Further, certain procedures, such as live-virus vaccinations, require inoculation with materials that may themselves be potentially infectious.

As such, numerous protocols and medical devices have been developed in order to minimize risks. In particular, safe needle handling, needle disposal practices, needle covers, and needle retractors help to prevent inadvertent needle sticks with contaminated sharps. Puncture site coverings and wound coverings protect others from contact with post-procedure exudate. Numerous types of absorbent and adhesive bandages are known in the art that can be applied to a puncture site or vaccination site on a patient. In general, these bandages include an absorbent material that covers the procedure site and an adhesive to keep the absorbent material in place and, in some cases, to isolate it. The bandages both protect the patient from microbial contamination of the broken skin while healing and also protect practitioners from the body fluids that can shoot, spray, or seep from the wounds. Although traditional bandages perform these functions, to a certain extent, they do not offer the advantages that accompany rapid deployment nor do they offer needle stick injury protection and shielding of microbial contamination during such a procedure. Further, in the prior art, it has not been possible to complete covering a procedure site prior to, or within moments of, completing an invasive procedure, because one hand was generally occupied performing the procedure while the other was occupied disposing of the contaminated sharp.

Therefore, it would be advantageous to have a procedure site dressing available to clinicians that overcame the above-cited disadvantages. In particular, it would be desirable to

have available a dressing that permitted the clinician to apply the dressing before performing an invasive procedure so that contaminated sharps could be discarded without the clinician having to simultaneously bandage the site. It would also be advantageous to have a dressing that permitted the clinician to intermittingly monitor and access the procedure site over time without requiring removal of the covering.

SUMMARY OF THE INVENTION

In view of the known deficiencies associated with earlier dressings, the present invention facilitates one-handed application of the dressing by providing a dressing and method whereby the dressing can be placed on the procedure site prior to the performance of an invasive medical procedure. When used prior to an injection or a vaccination procedure, such a device would decrease the time the person performing the medical service would be in possession of a contaminated sharp by allowing the completion of the bandaging procedure, using one hand, within a fraction of a second of completing the procedure. A device of this nature is in alignment with the intent of current needle stick injury prevention guidelines.

Because traditional bandages were developed when third party exposure to needle stick injuries and bloodborne pathogens was less of a concern, methods for using unique bandaging techniques to aid in the prevention and transmission of microbial exposure during an invasive procedure were not and did not then need to be incorporated into their design. By today's standards, traditional bandages are no longer adequate to protect healthcare workers from exposure to bloodborne pathogens because they are first applied *after* vaccinations, inoculations, injections, surgeries, or other such invasive medical procedures. Because traditional bandages are applied over the procedure site after the procedure, they therefore require manipulation of the site and the bandage, including wiping blood and other fluids from

the procedure site, removing any backing from the bandage, and properly securing the bandage to the site after such a procedure is completed. These necessary functions must all be performed while the medical practitioner is maintaining possession of or is attempting to simultaneously dispose of a contaminated needle or other sharp instrument. Otherwise, the medical practitioner must leave the site unattended while disposing of the contaminated sharp and then return to bandage the puncture site. This creates a hazardous scenario in that it becomes more likely that practitioners may either stick themselves, or others, with the sharp or contaminate themselves with the patient's body fluids while their attention is divided among these conflicting tasks or that the patient may touch and contaminate the procedure site while the practitioner is focused on proper sharps disposal.

The present invention is for an invasive medical procedure site dressing for use on humans or animals that includes an absorbent layer contacting the skin and defining an aperture through which the medical procedure can be performed. The absorbent layer absorbs fluids at the procedure site created by exudate from the wound and excess material from the procedure. Hingedly affixed to an upper surface of the absorbent layer and covering the aperture is a flexible door that protects the site after the procedure. The door may be transparent so that the site can be visually monitored as it heals or an expected reaction develops.

By providing a bandage that is placed over or near the procedure site prior to commencing the invasive part of the procedure, the bandage itself becomes part of the procedure's process and can be used to complete the bandaging process within moments of or synchronous with completing the procedure. This new syntax frees the provider to dispose of the contaminated sharp immediately, rather than after having maintained possession of the

contaminated sharp while simultaneously performing a bandaging procedure on the site with the other hand. The site dressing, along with the method for bandaging a medical procedure site prior to performing the procedure, decreases the healthcare provider's exposure to bloodborne pathogens. Furthermore, when the invention is being used in this surgical drape configuration, duplication of materials is prevented by permitting the surgical drape to double as the post-surgical bandage.

The dressing of the present invention includes a pull-tab, a hinge, an adhesive coated material, and optionally, an absorbent pad. The invention is a bandage that has at least one part that adheres to skin prior to a medical procedure. Once placed, the bandage remains clear of the operative field until it is needed. The section of the bandage that contacts the skin either has a portion removed to define an aperture where a procedure is to be performed or it is designed and configured in such a way that it can be placed close to the procedure site so as to infer the procedure's intended location from the positioning of specific components of the bandage. The present invention provides for a dressing that can be applied over, or near to, an invasive procedure site, prior to commencing the procedure. The present invention also provides for a dressing that can remain on, at, or near to the site during the procedure and can cover the site almost instantly after the procedure has been completed. Further, the present invention provides for a dressing that protects an invasive procedure site from contamination while it heals. Also, the present invention provides for a bandage that can cover a procedure site within moments of the completion of the procedure using only one hand, that can be used preemptively to prevent exposure of healthcare workers to bloodborne pathogens, and that can be re-opened to observe, evaluate, service, clean, or treat the site. The bandage will shield the healthcare provider from aerosols, sprays, and leakages of potentially contaminated fluids

during the course of the procedure. Also, the present invention provides for a bandage that can not only be applied prior the performance of an invasive procedure, but that can provide access later to that invasive site for observation or treatment.

The invasive medical procedure site dressing for use on humans or animals may include an absorbent layer or pad which may or may not contact the skin and which either defines the procedure site via an aperture in the bandage through which the medical procedure can be performed or is adhered to the skin in such a position on the body that the location of the procedure site is easily inferred from the shape or position of the bandage on the skin. If present, the absorbent layer absorbs the blood and/or the body fluids at the procedure site created by exudate, bleeding, or seepage from the wound or puncture hole at the procedure site.

The invention is comprised of a flexible, adhesive-coated material, which forms a door or a base layer flap and is hingedly affixed to the skin. Such base layer may be a simple strip of adhesive coated material, or it may be large enough to cover and surround the procedure site, even a major surgical site. The invention may be formed with the addition of a through and through aperture so it can be positioned in such a way as to fully surround the procedure site prior to the inception of a procedure such as an injection or a surgery procedure so it can remain in place to protect the site after the procedure is completed. It may have a layer of absorbent material between the base and the skin and surrounding the procedure site with the adhesive layer of the base bandaging material extended beyond the edges of the absorbent layer to make contact with the skin 360-degrees around the absorbent layer and hence encircle and protect the lesion. Such absorbent layer would, in many embodiments, have a through and through aperture coincident with the aperture of the base bandaging material. The absorbent

layer could, in fact, lack an aperture or its aperture could be smaller or larger than that of the base-bandaging layer. The door may be transparent so that the site can be visually monitored as it heals or as an expected reaction develops. The observation door made at least in part of a transparent flexible material may be hingedly affixed to a top surface of the patch base layer and may be provided in its open conformation as packaged.

If present, the aperture may be comprised of a material that limits the movement of bodily fluids, such as a closed cell foam, so as to prevent the fluids from escaping from the operative field or procedure site. The bandage may be of a size small enough to protect a patient and operator during a venous or arterial blood draw, vaccination, or injection procedure, or it may be large enough to perform the function of a surgical drape. Additionally, the through and through aperture may be covered or otherwise completely obscured by a material film, such as a thermoplastic elastomer, which is typically clear or translucent, non-coring, non-pyrogenic, and self-sealing. Such a film could be punctured by a needle or medical device during a procedure such as an injection and it would re-seal itself to keep body fluids within the cavity formed by the bandage and the film and the skin. By virtue of its self-sealing properties, such a membrane would provide an additional level of protection to the clinician from exposure to bloodborne pathogens and body fluids.

In one embodiment, the base layer may be absent completely and the hinge can be formed by a bend in the flexible door itself, which is now little more than a simple bandage which is fitted with the deployment method of the invention. In this embodiment, one side of the adhesive surface of the door would be affixed directly to the skin and a hinge would be formed out of much of the rest of the bandage. A piece of tape or flexible material, such as, but not limited to, polyethylene, polyurethane, or vinyl, which may be coated with adhesive on

one or both sides, can be used as the hinge. While the material is flexible and can be folded to use as a hinge, it is sufficiently rigid and springy so that it will maintain its shape, even under the burden of the full weight of the door (i.e., the body of the bandage), and it will hold the door open, when otherwise unstressed. This hinge material adhesively affixes the door to the bandage-body and holds the door open by functioning as a spring to keep the door open until such time as the door is deployed (i.e., closed) and the door's adhesive contacts the base of the bandage. The weight or flexibility of the door of this embodiment may be such that an additional adhesive may be needed on the back of the body of the bandage to temporarily adhere the top of the bandage's body of the bandage to the skin until the device is deployed. When closed, the adhesion of the door to the base or to the skin is greater than the strength or recoil of the hinge-spring and hence, the door stays closed. Also, the door may be held in its open position with a releasable adhesive bead located on the patch base layer.

In another embodiment, instead of a separate hinge, one edge of the door might be folded under in such a way that the adhesive of the door contacts the base and the release paper holds the door in place by an overlapping fold or second hinge which blocks the hinge from rotating but still allows the front section of the release paper to rotate and bring the absorbent pad down to the aperture. In yet another similar embodiment, the adhesive that holds the door and the base together when the device is closed (i.e., deployed) is on the base layer, rather than the door. In still yet another embodiment, the base layer is absent and the hinge material is adhered directly to the skin and holds the door open. If the door (or bandage or body, as the case may be) is too heavy, a bit of adhesive between the back of the bandage and the skin, to hold the bandage in its un-deployed configuration, may be necessary.

An important function of the door is that it remains clear of the operative field during

the procedure. This can be accomplished in a number of ways and hence altering the way in which the door is kept clear of the operative field can produce numerous embodiments of the invention without diverging from the scope of the invention. In one embodiment, the door is attached to the base by a separate flexible piece of adhesive coated tape that can fold and function as a hinge. This tape has enough flexibility for the door to be closed completely and enough rigidity to keep it open during the procedure and until needed. For example, the tape may be an adhesive coated polyethylene sheet. Closing the door brings its adhesive coating into contact with the skin or with the exposed surface of the base layer. When the adhesive makes contact with the skin or base surface, the adhesive overcomes the spring-tension of the hinge and holds it closed.

When closed, the observation door will cover the aperture. The observation door may further have attached in its top surface (when open) an absorbent pad sized to fill the aperture when the observation door is closed. This permits absorption of excess fluids at the site post-procedure. The absorbent pad may be removed from the door and discarded after use. The observation door is then closed again to protect the site from contamination. In a further alternative embodiment, the observation door may be opaque so that the site is not readily viewable by the casual observer. Alternatively, a second opaque outer door may be affixed over the observation door. Thus, the outer door blocks casual viewing of the procedure site, but can be easily lifted by the clinician for viewing of the site through the observation door.

In another embodiment, virtually the entire device is equivalent to the door and it is held in place by adhesives that limit the movement of the body of the bandage. In this embodiment, there is no separate base layer. This embodiment is essentially a simple bandage that is folded such that it incorporates the methods of this application to remain folded and

ready to deploy near a procedure site so it can be used preemptively as described herein.

The optional absorbent pad provides protection from exposure to bloodborne pathogens for a person giving an injection. To this end, the device is designed so it can be easily and rapidly deployed during an injection procedure, even before the needle has been fully removed from the patient. The embodiments designed for use with needle punctures include a flexible absorbent pad which is positioned in such a way that after the puncture has taken place and while the door is being closed, the flexible absorbent pad can easily be bent and brought into contact with the needle-skin interface. In this way, the invention performs the traditional function of covering the needle as it is removed to prevent spray or aerosol of body fluids and it puts pressure on the injection or blood draw site to help close the wound.

Since all skin puncture procedures should be performed using universal precautions, in a typical embodiment of this invention, the body of this device is made from materials which prevent the passage of blood, body fluids, and pathogens through from the lesion site to the outside surfaces of the bandage where someone could come in contact with the pathogens. For example, a thin layer of polyurethane is impervious to bacteria and viruses. Optionally, the body of the device potentially could be constructed from porous materials, if the specific function of preventing organic materials from reaching the surface were not an issue. A bandage of this type might be used for simple cuts and scrapes on healthy children, for example.

In another embodiment, perhaps as packaged for sale, the absorbent layer is sandwiched between a bottom coated release-paper carrier that is removed immediately prior to using the dressing, and a base layer of flexible material with an adhesive coated bottom surface for attaching the dressing to the procedure site. The absorbent layer and patch base

layer each define a procedure site aperture so that access to the procedure site is possible through both layers. In this embodiment, the adhesive of the patch base layer would typically extend beyond and surround the periphery of the absorbent layer so the adhesive of the base layer would envelop the absorbent layer and seal all absorbent materials and fluids and pathogens within the confines of the bandage.

In yet another embodiment, the invention is a simple bandage comprised of a strip of tape with a piece of absorbent material adhered, and generally centered, to its adhesive side, similar to the plastic bandaging strips commonly used for small cuts. This device would be folded and fitted with a mechanism that could hold it together such that one could adhere it to the skin in the folded configuration, ready to deploy, on the skin near a procedure site, such as an injection site. To deploy the device means, 'to close the bandage over and against the procedure site.' The retention mechanism could be a straight or folded piece of release-paper, typically coated for adhesive release on one side only, with the coated side facing the adhesive of the bandage and which may have a small piece of adhesive or adhesive coated material or adhesive coated film adhered to the non-release side of the release-paper or release paper with a section removed.

In yet another embodiment, the release-paper has no adhesive coating. Here, the release-paper has a section or sections removed which allows the adhesive from one portion of the bandage, which is otherwise covered by the release coated surface of the release-paper mechanism, to extend through or past the surface of the release-paper and adhere to the non-adhesively coated back of the other end of that same bandaging material and hence, hold the device in its locked and ready configuration until deployed. The materials of the bandage and release paper are very thin, and relatively small discontinuances in the release-paper easily

permit the adhesive of the bandage to pass through the release-paper to contact the non-adhesive back of the bandage and hold the embodiment cocked. One end of the release-paper can form a pull-tab to deploy the device and can be positioned in such a way that a section of the adhesive side of the body of the bandage can hold the bandage in place against the skin. The release-paper, in turn, is temporarily releasably adhered to the adhesive of the bandage strip. The adhesive coated or fenestrated end of the release-paper strip is positioned within the fold of the bandage against the back of the bandage in two places. Hence, using any of the preceding methods, the hinge is maintained in its fully open position until the release-paper tab is pulled and the release-paper is pulled free from its attachment(s) to the bandage. With the adhesive coated version of the release paper, once the adhesive coated end of the release-paper is pulled free of one side of the folded back of the bandage, the bandage is freed to rotate on its hinge in such a way that the bandage can be closed over the procedure site very quickly.

In yet another embodiment, there is an absorbent material positioned on the bandage in such a way that the absorbent material will cover the procedure site when the invention is deployed. The absorbent material may be fully circumscribed by the adhesive layer in such a way that when the device is deployed, a ring of adhesive coated material completely surrounds the absorbent material so as to surround the procedure site, and seal it within a ring of bandaging material. Else, the absorbent material may traverse the full width of the body of the bandage and hence, the procedure site would be covered by absorbent padding material. In this case, the procedure site would be covered, but it would not be completely isolated by an adhesive seal after the device was deployed.

In yet another embodiment, the site dressing has an aperture in the base and an

observation door, which may be made in part of a transparent, stiff, or flexible material, and is hingedly affixed to a top surface of the patch base layer and is provided in its "open" configuration as packaged. When closed, the transparent door, or a transparent part of the door, will cover the aperture and the procedure site, and will allow observation of the site without requiring removal of the bandage. The door may further have attached on its top surface (when open) an absorbent pad, cut to size to either fill the aperture or cover, without entering the aperture, when the door is closed. The door, whether transparent to permit ongoing site observation or opaque so as to obscure the site, may be closable and re-openable so as to permit repeated access to the site for observation or treatment. Such a function can be achieved by using a non-permanent re-positionable adhesive on the adhesive side of the door and may be enhanced by adding a non-adhesively coated tab to the edge of the door to assist in opening the door.

In the embodiment in which the pad fills the aperture, the pad assists post-procedure absorption of excess fluids at the site. Additionally, in the embodiment in which the pad covers but does not fill nor enter the aperture or one in which the pad enters the aperture but is not as thick as the base, and hence does not contact the skin when the door is closed, the pad and aperture form a chamber in which the procedure site can be enclosed, although the site itself is not actually touched by any of the bandaging materials. The absorbent pad may be attached to the adhesive surface of the door of the bandage, in which case it will remain with the device when it has been closed or it may be attached to the release-paper so that it can be disposed of immediately after the procedure has been completed when the release-paper, pull-tab closer/deployer component is removed from the device to fully deploy it. The absorbent pad can also be backed by a release paper layer, essentially the size of the pad, so it can be

removed from the door and discarded. These embodiments would be useful for burns or for vaccinations, such as smallpox vaccinations, where blotting the site could be useful.

In another embodiment, a piece of release material can be adhered to the adhesive surface of the door, such that pulling the tab would rotate the door on its hinge to close the door over the procedure site aperture with one single movement. In other alternative embodiments, the door can be clear, translucent or opaque, depending on whether, in the intended use, it is desirable for the procedure site to be readily viewable and it can be re-openable, or not.

The present invention further includes methods of applying dressings to human or animal tissue prior to the inception of an invasive procedure, such as an injection. The present invention includes methods of retaining the bandage in an un-deployed state and preventing it from prematurely entering the operative field. The invention provides a method for configuring bandages that can be positioned over or near a proposed invasive medical procedure site prior to the inception of the procedure. A base layer of the bandage is adhered adhesively to the skin and the design of the bandage keeps all parts of the bandage out of the operative field so that the procedure can be performed unimpeded. During the final moments of the procedure or as soon as the procedure is completed, the bandage can be rapidly deployed with one hand. The present invention provides for a method of applying bandages to a site, prior to the inception of an invasive procedure, and a method of preventing potentially obstructive parts of the invention from entering or obscuring the view of the operative field until the procedure is completed and the device is to be deployed.

Certain methods of folding, taping, placing, and deploying the bandages also disclosed in this application will greatly reduce the time it takes to complete the bandaging of a

procedure site after the procedure has been performed. One purpose of the invention is to shorten the time a healthcare provider is in possession of a contaminated sharp by decreasing the time it takes to complete the one-handed bandaging of an invasive procedure site once the procedure has been completed. Furthermore, because the bandage of the present invention is applied before the procedure is performed, not *after* performing a puncture, healthcare providers need not choose between disposing of a contaminated sharp, thus protecting themselves, and bandaging the site while maintaining possession of the contaminated sharp, thus protecting their patient. The surgical patient is protected from the potential infections that could occur when a fresh surgical site is unnecessarily handled during an immediate post-surgical bandaging procedure that could have otherwise been avoided by simply closing the window on the drape immediately after the surgical procedure is completed.

For a better understanding of the present invention, together with other and further objects thereof, reference is made to the following description, taken in conjunction with the accompanying drawings, wherein like numerals refer to like elements throughout the several views, and its scope will be pointed out in the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a top view of an embodiment of the present invention in its open configuration.

Fig. 2 is a top view showing the disassembled components making up the embodiment of Fig. 1.

Fig. 3 is a side view showing the disassembled components making up the embodiment of Fig. 1.

Fig. 4a is a side view of the embodiment shown in Fig. 1 in its open configuration.

Fig. 4b is a side view of the embodiment shown in Fig. 1 after use in its closed configuration.

Fig. 5a is a side view of an embodiment of the present invention in its open configuration.

Fig. 5b is a side view of the embodiment of Fig. 5a of the present invention after use in its closed configuration.

Fig. 6 is a perspective view of an embodiment of the present invention.

Fig. 7 is a top view of an embodiment of the dressing of the present invention in an open configuration.

Fig. 8 is a top view of the disassembled components of the embodiment of Fig. 7 of the present invention.

Fig. 9 is a side view of the disassembled components of the embodiment of Fig.7 of the present invention.

Fig. 10 is a side view of the embodiment of Fig. 7 of the present invention in a closed configuration.

Fig. 10a is an oblique top view the embodiment of Fig. 7 of the present invention in a partially closed configuration.

Fig. 10b is an oblique bottom view of the embodiment of Fig. 7 of the present invention in a partially closed configuration.

Fig. 10c is an oblique side view of an embodiment of the dressing of the present invention in a partially closed configuration.

Fig. 10d is an oblique top view of the embodiment of Fig. 10c of the present invention in a partially closed configuration.

Fig. 10e is an oblique top view of an embodiment of the dressing of the present invention in a partially closed configuration.

Fig. 10f is a partially disassembled view of the embodiment of Fig. 10e of the present invention.

Fig. 10g is an oblique top view of an embodiment of the dressing of the present invention.

Fig. 11 is a top view of an embodiment of the deployer and dressing of the present invention.

Fig. 11a is a bottom view of the embodiment of Fig. 11 of the present invention.

Fig. 11b is a bottom view of an embodiment of the deployer and dressing of the present invention.

Fig. 11c shows the first step in a folding sequence of the embodiment of Fig. 11b of the present invention.

Fig. 11d shows the second step in the folding sequence of the embodiment of Fig. 11b of the present invention.

Fig. 12 is a side view of an embodiment of the deployer and dressing of the present invention.

Fig. 12a is a folded view of the embodiment of Fig. 12 of the present invention.

Fig. 12b is an unfolded oblique view of the embodiment of Fig. 12 of the present invention.

Fig. 13 is a side view of the embodiment of Fig. 12 of the present invention.

Fig. 14 is an oblique view of the embodiment of Fig. 12 of the present invention.

Fig. 15 is a lateral view of an embodiment of the deployer and dressing of the present

invention.

Fig. 16 is an oblique view of the embodiment of Fig. 15 of the present invention.

Fig. 17 is a top view of the embodiment of Fig. 15 of the present invention.

Fig. 18 is a lateral view of an embodiment of a deployer and bandage of the present invention.

Fig. 19 is an oblique view of the embodiment of Fig. 18 of the present invention.

Fig. 20 is a lateral view of an embodiment of a deployer and bandage of the present invention.

Fig. 21 is an oblique view of the embodiment of Fig. 20 of the present invention .

Fig. 21a is a right oblique view of an embodiment of a deployer and bandage of the present invention.

Fig. 21b is a left oblique view of the embodiment of Fig. 21b of the present invention.

DETAILED DESCRIPTION OF THE PREFFERED EMBODIMENTS

Before discussing the structure of the invention in detail, note that the layers of materials used in the structure are quite thin. In the various figures, the thicknesses are sometimes exaggerated for clarity of illustration. In particular, layers of adhesive are usually not shown, as the adhesive is generally coated directly onto the components and is not technically a separate part. All adhesive coated parts are clearly identified and the sides and portions of the components that are adhesive coated are clearly defined. Recognize, also, that when exaggerations occur, they also exaggerate the curvatures that occur in the drawings at the overlapping intersections of various layers.

Figs. 1-4 are drawings of one embodiment of the present invention. Fig. 1 shows an embodiment of the present invention from above as it may be packaged before use. The

complete dressing is generally designated as **10**. The dressing **10** is composed of multiple components layered on top of each other to form the finished product. Fig. 2 shows each of the individual components forming the complete dressing **10**. Fig. 3 shows each of these components stacked, but separated from each other, from a side view. Referring to Figs. 1-3, the embodiment of the present invention shown in these figures includes an absorbent layer **34** sandwiched between a carrier paper **60** and a patch base layer **53**.

The carrier paper **60** acts as a backing for the entire dressing during packaging and shipping and is removed just prior to application of the dressing **10**. The carrier paper **60** is designed to affix to and release from an adhesive layer and so is composed of a material having these properties, for example, a plastic or waxed paper. Since the patch base layer **53** is slightly larger than the underlying absorbent layer **34**, the carrier paper **60** contacts the entire bottom surface of the absorbent layer **34** and a portion of the bottom surface of the patch base layer **53**.

The absorbent layer **34** directly contacts the skin at the medical procedure site when the dressing **10** is applied to the patient. The absorbent layer **34** must also be able to wick away fluids from the procedure site. As such, the absorbent layer **34** is composed of a material that is compatible with extended contact with human or animal skin and readily absorbs fluids. For example, the absorbent layer **34** can be composed of cotton, or other similar natural absorbent fibers or absorbent polyurethane. One of skill in the art would recognize other suitable materials alone or in combination having the dual qualities of absorbency and compatibility with human skin contact that would work equally well within the scope of the present invention. The absorbent layer **34** defines a procedure site aperture **35**

that passes completely through the absorbent layer **34**. The dressing **10** is placed over the procedure site so that the procedure site aperture **35** completely surrounds the procedure site with enough open space available for the procedure to be performed. The absorbent layer **34** may further have an adhesive coating on its bottom skin-contacting surface (not shown) that releasably adheres the dressing **10** to the procedure site so that separate bandaging materials are not required. The thickness of the absorbent layer **34** can vary depending on the particular needs of the procedure. For example, if the procedure is expected to produce a lesion of considerable height, the absorbent layer **34** can have a thickness greater than what might ordinarily be used. A thicker absorbent layer **34** may also be desirable when the procedure results in excess fluids. As a non-limiting example, the absorbent layer **34** of the embodiment can vary as needed between about $1/16^{th}$ of an inch and about one (1) inch.

The patch base layer **53** is positioned on top of the absorbent layer **34** and can extend beyond the edges of the absorbent layer **34**. The patch base layer **53** functions to mold the absorbent layer **34** to the contours of the skin and provide a waterproof barrier over the procedure site. It may also be desirable to use materials that are transparent. Therefore, the patch base layer **53** may be comprised of any material or materials, as is generally known in the art, that provides features that may include flexibility, non-toxicity, and transparency. For example, the patch base layer **53** can be made from any of a number of natural and synthetic polymers, including, but not limited to, rubber or polyurethane. The patch base layer **53** also defines a procedure site aperture **35** preferably of the same size and shape as the one formed through the absorbent layer **34**. The procedure site aperture **35** should be located on the patch base **53** so that when the dressing **10** is assembled, the apertures **35** formed through the

absorbent layer **34** and the patch base layer **53** line up so as to form an aperture through both these layers, providing a clear line of sight through the procedure site aperture **35** to the procedure site when the dressing **10** is applied. The patch base layer **53** may also have an adhesive coating on its bottom surface (not shown) both for the benefit of adhering the dressing **10** to the skin at the procedure site and for adhering the absorbent layer **34** to the patch base layer **53**. Preferably, the adhesive layer on the patch base layer **53** is sufficient to adhere the dressing **10** to the patient's skin so that an adhesive layer is not also required on the absorbent layer **34**.

An embodiment of the present invention may further include an observation door **50**. When disassembled, as shown in Fig. 3, the observation door **50** can be a flat sheet having a flap member **72** and a fixed member **96** joined to each other at a hinge **22**. When assembled as shown in Figs. 1, 4a and 4b, the fixed member **96** is folded under the flap member **72** at the hinge **22** and adhered to the patch base layer **50** with, for example, a permanent adhesive **93**. This conformation positions the observation door **50** in an open position, which is shown in Figs. 1 and 4a. The observation door **50** can be held in its open position by an adhesive bead **92** located on the patch base layer **53**. The adhesive bead **92** is a releasable adhesive so that the flap member **72** of the observation door **50** can be pulled free and swiveled on the hinge **22** to a closed position.

As shown in Fig. 4b, when the observation door **50** is placed in its closed position, the procedure site aperture **35** is covered and protected by the flap member **72** of the observation door **50**. Since the clinician may wish to observe the site over time without always needing direct access to the site, the observation door **50** may be made from a transparent material.

Alternatively, the flap member **72** of the observation door **50** may simply have a transparent window (not shown) through which the site can be observed, with the remainder of the observation door **50** constructed from an opaque material. Further, since the observation door **50** may also be closed for extended periods of time, it may be desirable to construct at least the portion of the flap member **72** covering the aperture **35** from a gas permeable material or provide small pores through the flap member **72**. Suitable materials with one or more of the above listed properties would be obvious to one of skill in the art. As non-limiting examples, such materials may include, but are not limited to, silicone and polyurethane, or other natural or synthetic polymers with minute pores throughout, as can be accomplished with lasers or other fine puncturing tools.

A releasable adhesive **75** can cover the top surface (when open) of flap member **72** so that when the flap member **72** is positioned in its closed position, the releasable adhesive **75** will hold the observation door **50** in its closed position. However, because the releasable adhesive **75** is releasable, the observation door **50** can be opened after it is closed so that access can again be gained to the procedure site. The flap member **72** may have a positioning tab **78** that facilitates moving the observation door **50** between its open and closed positions. The positioning tab **78** can be placed on a side opposite the hinge **22**, where it will likely be most effective.

The observation door **50** may have a conformation other than flat. For example, it may have a convex or bubble shape, beneficial if a lesion produced by the procedure reaches a thickness large enough that the thickness of the absorbent layer **34** is insufficient to keep the lesion from directly contacting the observation **50.** A convex shape to the observation door

50 could provide added height above the procedure site. Referring to Fig. 6, the dressing **10** could be initially applied until the lesion grew too large and then the entire dressing **10** is replaced with a simpler dressing **210** comprised of a flexible adhesive layer **250** similar to the patch base layer **53** defining an aperture **235** and surrounding an observation window **270** that is so steeply convex-shaped so as to form a dome over the lesion. The observation window **270** does not open to allow access to the site as does the observation door **50**. The dressing **210** may or may not include an absorbent pad, depending on the particular need.

As a further embodiment of the present invention, the dressing **10** may include an absorbent pad **40.** As shown in Figs. 1 and 3, the absorbent pad **35** can be mounted to a backing **62**, which in turn can be releasably affixed to the flap member **72** of the observation door **50**. The releasable adhesive **75** can hold the absorbent pad **35** backing **62** to the observation door **50**. The absorbent pad **40** can be made from any absorbent material, as would be generally known by one of skill in the art, with wicking properties and while also being compatible with contact with animal or human tissue. For example only, the absorbent pad **40** could be made from cotton or absorbent polyurethane. Further, the absorbent pad **40** can be constructed from the same material as the absorbent layer **34** or even cut from the absorbent layer **34**. Cutting the absorbent pad **40** from the absorbent layer **34** provides the added advantages of both saving on materials costs and assuring that the absorbent pad **40** is exactly the same diameter as the absorbent layer **34**, which then ensures a tight fit of the absorbent pad **40** within the absorbent layer **34**. Even further, additional absorbent pads (not shown) separate form the dressing can be provided if follow up cleansing of the procedure site is required at any time during the monitoring process.

In practice, the absorbent pad **40** facilities safe sharps handling by the practitioner. After the procedure is performed, the practitioner can simply close the observation door **50**, which brings the absorbent pad **40** in contact with the procedure site. If the absorbent pad **40** is sized to exactly fill the open space of the aperture **35**, then no further pressure application or adhesives are required to hold the absorbent pad **40** in place. Thus, the clinician can perform the procedure and easily swab and cover the procedure site with one quick motion. This leaves the clinician free to properly focus on safely discarding any contaminated sharps used during the procedure without further attention to the procedure site. The absorbent pad **40** will wick away any fluids from the procedure site and cover the site while the clinician attends to other matters. Once all the excess fluid has been absorbed away from the site, the absorbent pad **40** is removed from the observation door **50** by pulling the backing **62** away from the observation door **50** and then closing the door **50**. A removal tab **64** can be attached to the absorbent pad backing **62** to facilitate removal of the absorbent pad **40** and backing **62** from the door **50**. In one embodiment, the removal tab **64** is extended and the absorbent pad **40** is situated on the lower side of the extension in such a way that the act of removing the absorbent pad **40** by pulling the removal tab **64** to the left (as seen in Fig. 3) would rotate the observation door **50** on its hinge **22** to close the observation door **50** over the procedure site aperture **35** with one single movement.

It may be desirable to have a dressing wherein the procedure site is not generally visible for aesthetic reasons. In another embodiment of the present invention, an opaque outer door **180** can be affixed to a dressing **510**, as shown in Figs. 5a and 5b. The outer door **180** is positioned so that it covers an observation door **170** when both doors are in a closed position,

as shown in Fig. 5b. In Figs. 5a and 5b, the outer door **180** is placed so that a fixed member **186** of the outer door **180** is adhered with a permanent sealant **183** to a patch base layer **150**. A flap member **182** is then joined to the fixed member **186** by a hinge **184**. The hinge **184** permits the outer door **180** to pivot between an open (Fig. 5a) and a closed (Fig. 5b) position. The observation door **170** is then affixed to the outer door **180**. The exact placement of the outer door **180** is only relevant to the present invention in that when the outer door **180** is in its closed position, it covers a procedure site aperture **35** so as to prevent direct viewing of the aperture **35**. For example, the observation door **170** and the outer door **180** can both be hingedly affixed to the patch base layer **150** and the outer door **180** is still capable of concealing the aperture **35** when closed. In another example, the outer door **180** can be made by simply cutting away all but one edge of the patch base layer **150** so that a flap is formed that becomes the outer door **180**. The outer door **180** may also have a releasable adhesive on a surface so that the outer door **180** can be held in its closed position. If gas transfer to and from the procedure site is important, it may be desirable to either manufacture the outer door **180** from a gas permeable material, or apply the adhesive only to one edge of the outer door **180** so that gas can still transfer around the remaining open edges.

In another embodiment, the visible surface of the opaque outer door **180** when it is in its closed position can be decorated with colors or designs to provide a more pleasing outer appearance, since the patient may be required to wear the dressing **510** for extended time periods. For example, the outer door **180** can be stamped with children's cartoon characters, slogans or commercial logos. It would be obvious to one of skill in the art to provide an outer door **180** with appropriate designs and still remain within the scope of the present invention.

With the above embodiments of the present invention in mind, several non-limiting example procedures and a generalized method of using the embodiments are now provided. The dressing of the present invention is particularly useful for invasive procedures that require monitoring of the procedure site over time. For example, the dressing may be useful for minor surgical procedures such as suturing of lacerations or removal of small amounts of tissue. As another example, the dressing may be useful for certain invasive skin tests such as allergy testing or tuberculosis skin tests where the site must be repeatedly monitored for a reaction over time and yet needs to remain protected from the environment. Another example of a procedure in which the dressing of the present invention may be useful is for certain vaccinations that require periodic monitoring over time. For example, the current vaccination against Variola virus, the virus that causes smallpox in humans, is a live virus vaccine that must be closely monitored for development of a characteristic lesion. If no lesion develops, then it is likely the administered vaccine was ineffective at providing immunity against smallpox. However, in rare cases, the smallpox vaccine can stimulate a reaction that is excessive to the point of requiring further medical intervention. In either case, the vaccination site must be covered to protect the site from the environment (and conversely protect others from any infectious exudate produced at the site) and also regularly monitored. A dressing embodiment of the present invention satisfies both these requirements without the need for regular dressing changes. Additional uses for the dressings of the present invention will be evident to those of skill in the art.

In use, the clinician first cleans the site upon which the procedure is to be performed. Next, the dressing **10, 510** is affixed over the procedure site, for example by removing the carrier paper **60** and pasting to the skin. The medical procedure is then performed at the site

through the procedure site aperture **35**. The observation door **50, 170** is then closed and if an absorbent pad **40, 160** is present it is wedged into and enters the aperture **35**. The absorbent layer **34** around the aperture **35** and the absorbent pad **40, 160** together absorb any tissue exudate and excess procedure fluids present at the site. Meanwhile, the clinician is free to focus attention on safely disposing of any contaminated sharps and other materials. The absorbent pad **40, 160** is then removed and the observation door **50, 170** is closed. If an opaque outer door **180** is present, it may also be closed. Progress at the site over time is monitored by lifting the outer door **180**, if present, to its open position and viewing the site through the observation door **50, 170**. If access to the site is required (such as to absorb more exudate or otherwise clean the wound with an additional absorbent pad) the observation door **50, 170** can simply be raised to its open position and then closed again when the procedure is finished. While the patient is wearing the dressing **10, 510**, the site is protected from the environment. When the site has healed, the dressing **10, 510** can be removed. Thus, the patient does not have to be bothered with the discomfort and expense of continuously changing dressings over the course of procedure site monitoring and healing.

Figs. 7 through 10b depict an embodiment of the present invention. Referring to Figs. 7 and 8, the embodiment of the dressing **10** of the present invention is shown from above as it is open and may be packaged prior to use. The dressing **10** is composed of multiple components layered on top of each other to form the finished product. Referring to Figs. 9 and 10, the components of the dressing **10** are stacked from a side view. The dressing **10** has an optional carrier paper **60** coated with a release coating **61**, such as, for example only, silicone. The dressing **10** includes a door **50** with a back surface **52** removably adhered to the

carrier paper **60** with the release coating **61** on the carrier paper **60**. On the opposing side of the back surface **52** is the front surface **51**, upon which is centrally and adhesively positioned an absorbent pad **40**. A hinge **22** and a flexible material **20** connect the door **50** to the bandage body **30**. The base **31** of the bandage body **30** surrounds a lesion, wound, procedure site, etc. The bandage body **30** has an aperture **35** formed by a ring **33** to surround the lesion, wound, procedure site, etc. The bandage body **30** defines the procedure site aperture **35** that passes completely through the bandage body **30**. The dressing **10** is placed over the procedure site so that the procedure site aperture **35** completely surrounds the procedure site with enough open space available for the procedure to be performed.

The bandage body adhesive **32** on the bandage body **30** is removably adhered to the carrier paper **60** by the release coating **61** on the carrier paper **60**. The carrier paper **60** acts as a backing for the entire dressing **10** during packaging and shipping, and is removed just prior to application of the dressing **10**. The carrier paper **60** is designed to affix to and release from an adhesive layer and so is composed of a material having these properties, such as, for example only, a plastic or waxed paper. When the bandage body **30** is removed from the carrier paper **60**, the bandage body adhesive **32** is removably adhered to the skin of a subject.

The absorbent pad **40**, when the door **50** is rotated about the hinge **22** toward the bandage body **30** to close, may fit into the aperture **35** when completely closed. The absorbent pad **40** may directly contact the skin at the medical procedure site when the dressing **10** is deployed, that is, when the door is completely closed. Referring to Fig. 10, the dressing **10** in the deployed position is shown. In this embodiment, the absorbent pad **40** slightly protrudes through the aperture **35** once deployed and contacts the skin. In some embodiments, the

absorbent pad **40** does not encroach upon the aperture **35** when the invention is deployed. In all embodiments, the absorbent pad **40** should be able to wick away fluids from the procedure site. The absorbent pad **40** may be composed of a material that is compatible with extended contact with human or animal skin and readily absorbs fluids, such as, for example only, cotton or other similar natural absorbent fibers or absorbent polyurethane. One of skill in the art would recognize other suitable materials, alone or in combination, having the dual qualities of absorbency and compatibility with human or animal skin contact that would work equally well within the scope of the present invention.

The thickness of the absorbent pad **40** can vary depending on the particular needs of the procedure. For example, if the procedure is expected to produce a lesion that produces copious fluids, the absorbent pad **40** can have a thickness greater than what might be ordinarily used. As a non-limiting example, the thickness of the absorbent pad **40** of one embodiment can vary as needed between about $1/32^{nd}$ of an inch and about one (1) inch and may be partially cut-away to create room for an elevated lesion.

Referring now to Figs. 10a and 10b, the dressing **10** is shown in the partially deployed, or closed, position, with the door **50** rotated about the hinge **22**. The bandage body adhesive **32** molds the bandage body **30** to the contours of the skin and provides a waterproof barrier around the aperture **35** and over the procedure site. Transparent materials may be desirable. Therefore, the bandage body **30** may be comprised of any material or materials, as is generally known in the art that provides features that may include flexibility, non-toxicity, and transparency. For example only, the bandage body **30** can be made from any of a number of natural and synthetic polymers, including, but not limited to, rubber or polyurethane. The

procedure site aperture **35** in the bandage body **30** may preferably, but not necessarily, be of the same shape and slightly larger size as the absorbent pad **40**. In this embodiment, the procedure site aperture **35** is located on the bandage body **30** in such a position so that the aperture **35** formed through the bandage body **30** and the absorbent pad **40** line up such that the absorbent pad **40** fits cleanly and snuggly inside the aperture **35** and makes contact with the procedure site when the dressing **10** is applied and the door **50** is closed.

When the dressing **10** is deployed, the procedure site aperture **35** is covered and protected by the door **50**. Furthermore, and referring to Figs. 10c and 10d, since the clinician may wish to observe the procedure site over time without always needing direct access to the site, the door **50** may be made from a transparent material, and the absorbent pad **40** may be removable. In this embodiment, the absorbent pad **40** is positioned on a piece of release-paper backing **70** coated on a release tab **74**. The absorbent pad **40** is attached to the release-paper backing **70** with a releasable coating **71**. The release-paper backing **70** is, in turn, releasably affixed to the front surface **51** of the observation door with the releasable coating **71**. The combined component made of the absorbent pad **40** adhered to the release-paper backing **70** can be used to deploy the dressing **10** and then can be removed and discarded after the dressing **10** is deployed. Again, the absorbent pad **40** can be made from any absorbent material, as would be generally known by one of skill in the art, with wicking properties and compatible with animal or human skin contact, such as, for example only, cotton or absorbent polyurethane.

The observation door **50** may simply have a transparent window through which the site can be observed, with the remainder of the observation door **50** constructed from an opaque

material. Additionally, observation and treatment of the site may be further aided by using a non-permanent and re-positionable adhesive on the front surface **51** of the door **50**. This configuration would permit the door **50** to be opened as needed to access the site for care or observation. Further, the door **50** may have a conformation other than flat, such as a convex or bubble shape. A convex shape may be beneficial, for example, if a lesion produced by the procedure reaches a thickness large enough that the thickness of the bandage body **30** is insufficient to keep the lesion from directly contacting the door **50**. A convex or bubble shape to the door **50** would provide added height above the procedure site.

Further, since the observation door **50** may also be closed for extended periods of time, it may be desirable to construct at least a portion of the door **50** covering the aperture **35** from a gas permeable material or provide small pores through the door **50**. As non-limiting examples, such materials with the above-listed properties may include silicone, polyurethane, or other natural or synthetic polymers with minute pores throughout, as can be accomplished with lasers or other fine puncturing tools. The door **50** may be made of a solid material or it may have holes, vents, or pores in it to allow the site to breathe and help prevent moisture buildup. The vented door **50** may or may not be covered by a semi-permeable membrane that would prevent micro-organisms from passing either way through the door, but would allow moisture to exit the procedure site to help keep the humidity from building up under the door.

In practice, the absorbent pad **40** facilitates safe sharps handling by the practitioner. After the procedure is performed, the practitioner can simply close the door **50**, which brings the absorbent pad **40** close to or in contact with the procedure site. If the absorbent pad **40** is sized to exactly fill the open space of the aperture **35**, then no further pressure application or

adhesives is required to hold the absorbent pad **40** in place. Thus, the clinician can perform the procedure and then easily swab and cover the procedure site with one quick motion. Additionally, the absorbent pad **40**, whether the same size as the aperture **35** or larger, can be pushed against the needle barrel and the skin as the needle barrel is being removed from the tissue after a needle puncture has been performed. In this position, the absorbent pad **40** and door **50** can be used to shield the clinician from the blood splatter or aerosol which could occur from the puncture or from the triggering of a retractable type safety needle. Once the needle clears the aperture **35**, the door **50** can be fully closed so that the front surface **51** of the door **50** contacts the base **31** of the bandage body **30** and seals the site closed. This allows the clinician to focus on safely discarding any contaminated sharps used during the procedure without further attention to the procedure site. The absorbent pad **40** will wick away any fluids from the procedure site and cover the site while the clinician attends to other matters. The material of the bandage body **30** forms an adhesive 360° ring **33** around the procedure site. Once the door **50** is closed, and the dressing **10** is thus in the deployed position, the front surface **51** of the door **50** adheres the door **50** to the base **31** of the bandage body **30**, and a complete seal is formed over the procedure site.

Referring now to Fig. 10c and 10d, the absorbent pad **40** is adhered to the removable release tab **74**, which can be completely removed from the dressing. Once the excess fluid has been absorbed away from the site, the absorbent pad **40** can be removed from the observation door **50** by pulling the release-paper backing **70** away from the observation door **50** and then closing the door **50**. The absorbent pad **40** may be adhesively attached to a graspable release tab **74** to facilitate removal of the absorbent pad **40** and release-paper backing **70** together

from the door **50**. The release tab **74** is extended and the absorbent pad **40** is situated on the lower side in such a way that the release-paper backing **70** can be rotated towards the bandage body **30** and the absorbent pad **40** still attached to the paper release- paper backing **70** can be placed against a needle shaft or puncture site and then the door **50** can be re-opened. Next, pulling the release tab **74** away from the door **50** would rotate the door **50** on its hinge **22** to close the door **50** over the procedure site aperture **35** with one single movement and the release-paper backing **70** and the absorbent pad **40** are removed together from the front surface **51** of the door **50**. The release-paper backing **70** with the door **50** can then be discarded as a single piece.

As an example of use, the clinician first cleans the site upon which the procedure is to be performed. Next, the dressing **10** is affixed over the procedure site by removing the carrier paper **60** and affixing the patch to the skin by pressing the bandage body adhesive **32** against the skin. The medical procedure is then performed at the site through the procedure site aperture **35**. The door **50** is then closed and if an absorbent pad **40** is present, it enters and is wedged into the aperture **35**. The absorbent pad **40** absorbs any blood, tissue exudate, and excess procedure fluids present at the site. Meanwhile, the clinician is free to focus her attention on safely disposing of any contaminated sharps.

Referring now to Figs. 10e and 10f, two layers have been added to add a level of safety to the invention. Only the numeric designations that refer to the two new layers are shown in these drawings. One of the additional layers is an injection material **90**, which is a clear or translucent non-coring, flexible, self-sealing, non-pyrogenic material such as certain formulations of thermoplastic elastomeric film. The injection material **90** completely covers

the aperture **35** and can be held in place over the aperture **35** by a ring of film adhesive **91** between the underside periphery of the aperture **35** and the base **31** of the bandage body **30**. An additional layer of material, a retaining layer **80**, can be layered over the injection material **90** to hold the injection material **90** in place. The retaining layer **80** can have the necessary qualities of the injection material described above or it **80** can have a retaining layer aperture **85** to expose and create unimpaired access to the injection material **90**. The adhesively coated retaining layer bottom **83** adheres to the top surface of the injection material **90** at the periphery **73** and to the base **31** of the bandage body **30**, and thus holds the injection material **90** firmly in place on the bandage body **30**. The retaining layer **80** can be transparent, translucent, or opaque.

The retaining layer **80** and the injection material **90** provide an additional layer of protection between the procedure site and the healthcare provider. An injection can be performed by penetrating the injection material **90** with a hypodermic needle on a syringe. Most or all blood or body fluid loss that may occur beneath the injection material **90** will remain on the patient's side of the injection material **90** even after the needle is removed because the hole created by the needle closes and seals itself as the needle is removed due to the properties of the injection material **90**. In the event of bio-hazardous materials passing through the injection material **90** and staying on the surface of the injection material **90**, closing the door **50** will isolate the bio-hazardous material by sealing it under the door **50**, which is generally made to include a layer which is impervious to the typical biohazards of bacteria and viruses.

Referring now to Fig. 10g, there are clearly other ways to hold the door **50** open and to

attach the door **50** to the base **31** without changing the invention to observe the procedure site through the aperture **35**. For example, instead of a separate hinge **22**, one edge of the door **50** may be folded under in such a way that the adhesive of the door **50** contacts the base **31** and the release-paper backing **70** holds the door in place by an overlapping fold **76** which blocks the hinge **22** from rotating but still allows the front section of the release paper **77** to rotate and bring the absorbent pad **40** down to the aperture **35**. Also, the adhesive that holds the door **50** and the base **31** together when the dressing **10** is deployed (i.e., closed) may be on the base **31**, rather than on the door **50**. Furthermore, the bandage body **30** may be completely absent and the flexible material **20** near the hinge **22** may be adhered directly to the skin. If the door **50** is too heavy, a bit of adhesive between the back surface **52** of the door **50** and the skin, to hold the dressing **10** in its un-deployed configuration, may be necessary.

Referring next to Figs. 11, 11a, 11b, 11c and 11d, a deployer **100** is presented having a deployer aperture **122** placed at the end of the flexible release-paper **110**. The versions of the device shown here demonstrates one more of the nearly unlimited conformations of the deployers **100**. In this embodiment, the deployer component **100-1** consists only of the flexible release-paper **110** with some strategically placed deployer apertures **121**, **122** in, at, or near one end **119** of the flexible release-paper **110**. When the device is folded, as in Figs. 11c and 11d, the absence of material between the adhesive flap **223b** and the bandage back flap **222a** at the deployer apertures **121**, **122** allows the adhesive flap **223b** to contact and adhere to the bandage back flap **222a**. Since the adhesive flap **223b** extends through the deployer apertures **121**, **122**, it will the adhere adhesive flap **223b** to the non-adhesive surface of the bandage back flap **222a** when folded at a potential hinge location **229a** (see also Fig. 12) to

create the deployer hinge **229** and to bring the adhesive flap **223b** into contact with the bandage back flap **222a** through the deployer apertures **121**, **122**. Note that the flexible release-paper **110** and the bandaging material **220** are very thin and flexible; therefore there is little to prevent the adhesive flap **223b** from contacting the bandage back flap **222a** through the deployer apertures **121**, **122**. Also, note that the deployer aperture **121** through flexible release-paper **110** of Fig. 11b are different sizes, shapes, and locations than the deployer aperture **122** of Fig. 11a, demonstrating how different structural embodiments of this invention are still the same invention. Both the embodiments of Fig. 11a and Fig. 11b are folded exactly like embodiments of Figs. 15-17, see below, as is demonstrated by Figs. 11c and 11d.

Fig. 11b shows the embodiment of Figs. 11 and 11a with wedges removed from the end **119** of the flexible release-paper **110** to form the deployer apertures **121**. The invention with this embodiment functions exactly as does the that of Fig. 11a, demonstrating that various configurations that permit the formation of the deployer hinge **229** by adhesively attaching the bandage back flap **222a** to the adhesive flap **223b** are different embodiments of the same invention.

The bandage component **100-2** of the deployer **100** is comprised of a bandaging material **220**, such as a cloth or polyurethane material with a bandage adhesive coating **223** on one side and a cloth, plastic, polyurethane, or other non-adhesive bandaging material on the non-adhesive back **222**. Many different materials and shapes and sizes of bandages could conform to the specifications and requirements of this component. One skilled in the art could easily substitute one bandaging material for another to construct another embodiment of

the invention. The absorbent pad **40** is adhered to the bandage adhesive coating **223** at the adhesive flap **223b**. In this embodiment, the bandaging material **220** has a very thin polyurethane layer laminated on the non-adhesive back **222**.

In the embodiment shown in Figs. 11 through 14, the bandage body **30** shown previously in Figs. 7 through 10g is absent. Fig. 12, 12a and 12b, show an embodiment of the deployer **100** prior to being folded into the useable configuration shown in Figs. 13 and 14. Fig. 12 shows the deployer component **100-1** and the bandage component **100-2** in contact with one another. Folding the flexible release-paper **110** twice and the bandaging material **220** once completes this embodiment of the invention. In Fig. 12b, the two assemblies, the deployer component **100-1** and the bandage component **100-2**, which are combined to form the deployer **100**, are shown. The deployer **100** is comprised of a flexible release-paper **110**, such as, for example only, paper coated with silicone on the deployer component bottom **116** and uncoated on the deployer component top **115**. Also, the deployer **100** is comprised of a small piece of that same coated-material **140** and a piece of adhesive tape **130**, coated on both sides with adhesive, which holds the invention in its closed configuration. The adhesive tape **130** is sandwiched between the non-coated sides of the two pieces of coated material **140** and flexible release-paper **110** at one end of the flexible release-paper **110**. The combination of these three components forms the deployer component **100-1** for the deployer **100** of the embodiment of Fig. 12. Referring to Fig. 12b, in the construction of the deployer component **100-1**, as an alternative to the adhesive tape **130**, the end of the flexible release-paper **110**, from left edge **118** to right edge **117**, can be coated on one or both sides with a re-positionable adhesive or can have deployer apertures **121**, **122** as seen in Figs. 11a and 11b.

Fig. 12b shows how the deployer component **100-1** and the bandage component **100-2** are aligned prior to their being adhered together. The potential hinge location **229a** where the bandage component **100-2** will be folded is shown as a dotted line. In Figs. 12 and 12b, the potential left bend **113a** and the potential right bend **114a** will be locations of the left bend **113** and the right bend **114**, respectively, as shown in Fig. 12a of the deployer component **100-1**. The location and number of bends in general are almost arbitrary and there are many different location and numbers of bends in the flexible release-paper **110** that would give similar results and create the same invention.

To deploy the deployer **100**, the flexible release-paper **110** is bent to about 170-degrees in the down direction, as shown in Figs. 12 and 12b, at the potential left bend **113a** and then bending the flexible release-paper **110** back about 189-degrees at the potential right bend **114a** to produce the left bend **113** and the right bend **114**, respectively, as shown in Figs. 12a, 13, and 14. The adhesive tape **130** will be positioned in between the bandage back flap **222a** and the bandage front flap **222b** on the non-adhesive back **222** of the bandaging material **220**. Adhesively apposing bandage back flap **222a** and bandage front flap **222b** holds them together and creates the deployer hinge **229**. The chosen shape of the final flexible release-paper **110** is one of many choices for the bend locations and configurations and are shown as non-limiting examples. Referring now to Fig. 13, the exposed end **112** of the bandage component **100-2** then becomes a pull-tab **111**, which is used to deploy the device by pulling it in the direction of left bend **113** and then pulling it back in the direction of the right bend **114** to rotate the bandaging material **220** around the deployer hinge **229**. This motion straightens out the bandage against the skin or can be used to bring the absorbent pad **40** to the

skin surface. Once the pull-tab **111** is pulled in the direction of the right bend **114**, there is shear created between the adhesive on the adhesive tape **130**, where it is adhered to the bandage back flap **222a**, and the release-paper end **125**. The release-paper end **125** is inside of the space between the bandage back flap **222a** and the bandage front flap **222b**. The adhesive does not go all the way to the lower edge **224** of the non-adhesive back **222** of the bandaging material **220**. Hence, when the pull-tab **111** is pulled, some of the adhesive on the skin side adhesive surface **223a** remains adhered to the skin before the shear begins, so the adhesive tape bottom **130b** on the lower edge **224** of the flexible release-paper **110** can pull free from the non-adhesive back **222** of the bandaging material **220** without pulling the skin side adhesive surface **223a** away or off of from the skin. The flexible release-paper **110** remains adhered to the non-adhesive back **222**, while the bandaging material **220** is being rotated around the deployer hinge **229**. Until the bandaging material **220** is rotated around the release-paper end **125**, the flexible release-paper **110** remains adhered to the surface of the bandaging material **220** by some part of the adhesive tape **130**, depending on the adhesive qualities of the adhesive tape **130**. Further pulling the pull-tab **111** will free the deployer component **100-1** to be discarded, and will leave the bandage component **100-2** with the bandage adhesive **223** and absorbent pad **40** against the skin.

Folding the invention into the shape shown in Figs. 12a, 13, and Fig. 14 completes the device. Folding the bandage component **100-2** at the potential hinge location **229a** brings the non-adhesive bandage back flap **222a** and the non-adhesive bandage front flap **222b** to face one another to be held together by the adhesive tape **130** of the flexible release-paper **110**. The non-adhesive side of the bandage is held in place by the adhesive components of the

adhesive tape **130**, which locks the embodiment, until deployed, in the unused and hinged position. There are numerous methods of holding the deployer hinge **229** locked in this open position near the procedure site.

With the above embodiments of the present invention in mind, several non-limiting example procedures and a generalized method of using the embodiments are herein provided. To deploy the deployer **100** during an injection procedure as an example, the deployer is positioned on the skin with the deployer hinge **229** close to where the injection is to be performed, about half the distance from absorbent pad left edge **231** and absorbent pad right edge **232**. Hence, assuming a non-limiting 1 inch length, from the absorbent pad left edge **231** to the absorbent pad right edge **232**, the deployer hinge **229** will be about ½ inch from the proposed procedure site.

Once a needle is inserted, either the pull-tab **111** or the release **109** at the right bend **114** is pulled in the direction of the deployer hinge **229**. This movement pulls one side of the adhesive tape bottom **130b** off of the bandage back flap **222a** of the body of the bandaging material **220** and rotates the absorbent pad **40** around deployer hinge **229**. The absorbent pad **40** is rotated all the way to the skin where the needle is inserted. The absorbent pad **40** is pressed against the needle barrel and the skin. As the needle is removed from the puncture, pressure with the pad **40** on the puncture site is maintained. The needle retraction is performed with the absorbent pad **40** and the bandaging material **220** shielding the needle to reduce the chance that any spray or aerosol from the procedure site could reach the clinician. Once the needle and the syringe fully clear the operative field, the adhesive flap **223b** is pressed against the skin to complete the bandaging process. Then the pull-tab **111** is pulled

towards the end of the bandaging material **220**, the deployer component **100-1** is pulled away from the non-adhesive back **222** and the adhesive tape **130** is pulled off of the body of the non-adhesive back **222**. The clinician then sets the adhesive by pressing the bandage against the skin from one end to the other. The deployer component **100-1** is then discarded and the procedure is complete.

The dressing of the present invention is particularly useful for invasive procedures that could lead to infections or needlestick injuries to second parties. For example, the dressing may be useful for minor surgical procedures such as suturing of lacerations or removal of small amounts of tissue. As another example, the dressing may be useful for certain invasive skin tests, such as allergy testing or tuberculosis skin tests, where the site must be repeatedly monitored for a reaction over time and yet needs to remain protected from the environment. Another example of a procedure in which the dressing of the present invention may be useful is for certain vaccinations. For example, the current vaccination against Variola virus, the virus that causes smallpox in humans, is a live virus vaccine. That means that every needle is not only assuredly contaminated with a somewhat virulent live virus, many of them may be contaminated with other very virulent microorganisms. A dressing embodiment of the present invention decreases the time that a clinician would be exposed to contaminated needles and hence would increase the safety of the procedure. Additional uses for the dressings of the present invention will be evident to those of skill in the art.

Referring now to Figs 15, 16, and 17, this embodiment varies from the previous embodiment in the way the bandage and the flexible release-paper **110** are folded, and, as in another embodiment described fully herein, the flexible release-paper **110** has adhesive only on the non-coated side of the end of the paper. Adhesive tape top **130A**, as shown in Fig. 13,

is absent from this embodiment. Fig. 17 is shown on a carrier paper **60** as it might be placed before being packaged.

Figs. 18 and 19 show another embodiment of the deployer **300**. It uses the same components as the embodiment of Fig. 12, but they are combined for use in a different way. The coated surface of the deployer component bottom **116** of the deployer component **110-1** faces the adhesive flap **223b** of the bandaging material **220**. The end of the flexible release-paper **110** most distant from the deployer hinge **229** has an adhesive coating bottom **130a** on the adhesive tape **130** on the coated side of the deployer component bottom **116** of the flexible release-paper **110**. The absorbent pad **40** is located around the deployer hinge **229** and is bent with the deployer hinge **229** in such a way that the deployer **300** can be lifted away from the carrier paper **60** without touching the bandage adhesive **223** and the adhesive coating bottom **130a**, and the skin side adhesive surface **223a** can be pressed and adhered against the skin to hold the device **300** in place while the procedure is being performed. The device deploys by lifting the pull-tab **111** to pull the flexible release-paper **110** coated release-surface of the deployer component bottom **116** away from the adhesive flap **223b** of bandaging material **220**. When this pull-tab **111** pulls the flexible release-paper **110** free of the bandaging material **220**, the bandage is free to rotate on the deployer hinge **229**, bringing the adhesive flap **223b** in contact with the skin and the surface of the absorbent pad **40** into contact to cover the procedure site. With the skin side adhesive surface **223a** and the adhesive flap **223b** holding the absorbent pad **40** against the site, the bandaging material **220** is fully adhered in place over the procedure site. Pulling the pull-tab **111** such that the adhesive tape **130** is pulled off of the skin frees the deployer component **100-1** to be discarded and completes the

procedure. Note, in this embodiment as shown, the absorbent pad **40** traverses the entire width of the bandaging material **220**. An absorbent pad **40** not as wide as the bandaging material **220** would have bandage adhesive **223** borders all the way around its periphery and hence, when the bandage was deployed, the bandage adhesive **223** would form a seal around the absorbent pad **40** to fully isolate any potential infectious material under the bandage and within the sealed area.

Referring now to Figs. 20 and 21, an embodiment of a deployer **400** is shown which uses a weakly adhered backing **410** as the non-adhesive back **222** of the bandaging material **200**. This embodiment might be used to preemptively deliver a very thin bandaging material **220**, such as a 1-mil polyurethane, to the skin without damaging the bandage. Here, the absorbent pad, the door, the hinge and the adhesive bandage combine to form one integral component without defining an aperture. This embodiment takes advantage of commercially available raw bandaging materials which have release layers of the weakly-adhered backing **410** laminated to the non-adhesive back **222** of the bandaging material **220**. The procedure site is inferred from the location of the deployer hinge **229** and the location of the absorbent pad **40** and the deployer hinge **229** is retained in its open position and prevented from obscuring the operative field by a component which is either a weak adhesive or a mechanical restraint on the bandage, positioned so as to hold the device in its open configuration and so to define the deployer hinge **229** and to maintain the deployer hinge **229** in its open position until the device is deployed. The adhesive may be of a type that is non-permanent and is repositionable. Using an adhesive of this type, the door could be deployed and then put back in its hinged position several times during the course of a procedure. Here, the embodiment

has a more permanent type of adhesive, two pieces of double sided tape or a coating of adhesive on the flexible release-paper **110** where the adhesive tapes **130**. This adhesive tape **130** attaches the flexible release-paper **110** to a layer of weakly-adhered backing **410** which is weakly bonded to the non-adhesive back **222** of the deployer component bottom **116** of the bandaging material **220**.

A non-limiting example of a material that can be used to make this deployer **400** is a clear thin polyurethane bandaging material **220** with a loosely bonded layer of polyethylene weakly-adhered backing **410** on the non-adhesive back **222** of the bandaging material **220**. As a clarifying example of materials that might be used for this embodiment, 3M and Avery Dennison both manufacture materials of this nature, which are specifically designed to have a polyethylene for the weakly-adhered backing **410** removed from a thin film of polyurethane after the film adheres to the skin. At the time of this writing, the 3M material is experimental, is labeled MSX-6010 and is not commercially available, and the Avery Dennison material is labeled MED5030 and is commercially available. This embodiment is similar to an embodiment that would include the weakly bonded adhesive tape **130**, which holds open the embodiment of Figs. 11-14, except that it can be used to deliver very thin bandaging materials, such as .7 mil polyurethane, which can not be easily handled by themselves because they are very thin and adhesive coated on one side. Materials such as thin polyurethane films are often less than 1 mil thick.

Before deployment, the deployer **400** has the absorbent pad **40** bent at about 180 degrees in such a way that it can be grasped with two fingers, one on the flexible release-paper **110** at the pull-tab **111** and the other between the absorbent pad **40** and the carrier paper **60** at the lower absorbent pad surface **43**. Then the device can be easily adhered to the skin at

bandaging material **220** skin side adhesive surface **223a** and pressure can be put on the flexible release-paper **110** at a pressure point **117** to help to set the adhesive to the skin. This enhancement, which creates an easily to handle bandage, is also applicable to other embodiments. The double-stick adhesive tape **130** and the weakly-adhered backing **410** are functionally quite equivalent as both are meant to hold the device in its folded configuration until deployed and then both are cleanly removed from the non-adhesive back **222** of the bandaging material **220**, only in one case, there is an additional weakly-adhered backing **410**, possibly polyethylene, between the adhesive tape **130** and the non-adhesive back **222**. Here, temporary weakly-adhered backing **410** is affixed to the non-adhesive back **222** of the bandaging material **220** and that weakly-adhered backing **410** is folded, along with the material of the base of the bandaging material **220** to form the deployer hinge **229**. The weakly-adhered backing **410** would then be adhesively held in a folded position such that when the device was deployed by pulling the flexible release-paper **110** at the pull-tab **111**, the weakly-adhered backing **410** would be peeled off or pulled away from non-adhesive back **222** of the bandaging material **220** so that the deployer hinge **229** would close, that is be deployed and rotate to flat, and that rotation would bring the entire layer of bandage adhesive **223** of the polyurethane, for example, bandaging materials **220** against the skin where the bandaging materials **220** are fully adhered with the absorbent pad **40** covering the procedure site.

Referring now to Figs. 21a and 21b, embodiments show an alternative folding method, an alternative absorbent pad placement, and an alternative double-sided tape placement. Here, the deployer hinge **229** is offset and the adhesive tape **130** and its **130** adhesive coating bottom

130a are aligned to the backing edge **411** in such a way that when the deployer is deployed, the adhesive tape **130** at the adhesive coating bottom **130a** pulls the weakly adhered backing left **410a** cleanly away from the bandaging material **220**. The adhesive tape **130,** or adhesive coating if it has no tape core, is shown as much thicker than it actually would be to emphasize that the adhesive fills the space between the deployer's **400** weakly adhered backing left **410a** and weakly adhered backing right **410b** and prevents these two backing sections from being separated. Hence, when the pull-tab **111** is pulled, the thin layer, such as polyurethane, of the bandaging material **220** at the skin side adhesive surface **223a** stays adhered to the skin and the weakly adhered backing **410** pulls away from the non-adhesive back **222** and stays with the flexible release-paper **110** and the adhesive tape **130**. Next, rotation about the deployer hinge **229** occurs to bring the adhesive flap **223b** and the absorbent pad **40** to the skin where they remain adhered and the weakly-adhered backing **410** with the flexible release-paper **110** and the adhesive tape **130** are removed as one piece and discarded. An additional feature of this embodiment is visible at the lower edge **224** of the bandaging material **220** which can be seen to be slightly shorter than the weakly-adhered backing **410**, the backing end **411** extending beyond the lower edge **224** of the bandaging material **220**. In effect, when the device is deployed and the adhesive coating bottom **130a** pulls on the weakly-adhered backing **410**, the skin side adhesive surface **223a** of the bandaging material **220** adheres to the skin and creates a shear that helps to cleanly separate the weakly-adhered backing **410** from the bandaging material **220**.

While certain advantageous embodiments have been chosen to illustrate the invention, it will be understood by those skilled in the art that various modifications can be made herein

without departing from the scope of the invention. For example, the geometric configurations shown in the illustrative embodiments are generally rectangular and folded once or twice. However, depending upon the type of procedure, the dressing shape, folds, adhesive locations, and materials may be changed in accordance with those needs without diverting from the scope and spirit of the invention. Likewise, dimensions may similarly be varied according to need and still fall well within the scope of the present invention.